

UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 09-1093

UNIVERSAL HEALTHCARE/KING,

Petitioner,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition for Review of a Decision of the United States
Department of Health and Human Services. (A-08-107)

Argued: October 28, 2009

Decided: January 29, 2010

Before MOTZ and GREGORY, Circuit Judges, and Benson E. LEGG,
United States District Judge for the District of Maryland,
sitting by designation.

Petition denied by unpublished per curiam opinion.

ARGUED: Joseph L. Bianculli, HEALTH CARE LAWYERS, PLC,
Arlington, Virginia, for Petitioner. Erica Cori Matos, UNITED
STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Atlanta, Georgia,
for Respondent. **ON BRIEF:** Peter D. Keisler, Assistant Attorney
General, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.;
David S. Cade, Acting General Counsel, Dana J. Petti, Chief
Counsel, Region IV, UNITED STATES DEPARTMENT OF HEALTH & HUMAN
SERVICES, Atlanta, Georgia, for Respondent.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Universal Healthcare ("Universal") is a skilled nursing facility that provides care to Medicare beneficiaries in North Carolina. Universal appeals a final agency decision of the Secretary of Health and Human Services ("Secretary"). The Secretary, acting through the Centers for Medicare and Medicaid Services ("CMS"), imposed civil monetary penalties on Universal for non-compliance with several Medicare regulations related to residents' well-being and safety. Both an administrative law judge ("ALJ") and the Department Appeals Board ("Board") upheld CMS's findings of non-compliance and its assessment of the penalties.

Following the procedure in these cases, Universal has appealed the Board's decision directly to the circuit court. There are two determinations for us to make. The first is whether the Secretary's findings of non-compliance are supported by substantial evidence. The second is whether the monetary penalties are proportionate to the degrees of non-compliance. Because the Secretary's findings are supported by substantial evidence, and because Universal has failed to show that the civil penalties are clearly erroneous, we affirm.

I.

To participate in Medicare and Medicaid programs, skilled nursing facilities must comply with regulations set forth at 42 U.S.C. § 1395i-3 and 42 C.F.R. § 483. To determine whether a facility is in compliance, the Secretary contracts with state agencies, which conduct inspections known as surveys. 42 C.F.R. § 488.10 (2009). The surveys are conducted by multi-disciplinary, formally trained teams, each of which is comprised of at least one registered nurse. Id. § 488.31.

During the surveys, the state agency records any deficiencies that it discovers, including their severity. Id. § 488.404(b). The severity categories range from “[n]o actual harm with a potential for minimum harm” to those that pose “immediate jeopardy to resident health or safety.” Id. § 488.404(b)(1). A facility is considered to be in substantial compliance with the regulations if its deficiencies are ones that pose no greater risk than the potential for minimal harm. Id. § 488.301.

Once a deficiency has been identified, CMS selects a remedy to address it. Id. § 488.408. One potential remedy is a civil monetary penalty, which CMS may impose on a per-day or per-instance of non-compliance basis. Id. § 488.430.

A skilled nursing facility has the right to appeal CMS’s decisions. 42 U.S.C. § 1395cc(h) (2006). The first level of

appeal is to an ALJ in the Department of Health and Human Services. 42 C.F.R. § 498.44. The ALJ is empowered to hold a hearing and to take testimony. Id. § 498.60. The second level of appeal is to the Department Appeals Board. Id. § 498.80. Appeals to the Board are on the record. Id. § 498.86. An appeal of the Board's decision is taken directly to circuit court. 42 U.S.C. § 1395cc(h).

The North Carolina State Survey Agency completed surveys at Universal on November 22, 2005 and December 10, 2005. Both surveys found violations of federal requirements. The November violations centered on a patient, "G.J.," whose treatment plan called for him to receive a pain medication, Cafergot, each morning after he awoke.¹ The survey team found that on the morning of November 19, 2005, the on-duty nurse was unable to give G.J. Cafergot because the facility's pharmacy had run out of the drug. The nursing staff substituted Darvocet and failed to obtain a reorder of Cafergot until that afternoon.

Following the November survey, CMS notified Universal that its treatment of G.J. violated two Medicare regulations. The first regulation requires that a facility provide pharmaceutical services adequate to meet the needs of each resident. 42 C.F.R.

¹ This resident is referred to as Resident #1, or R1A, in the record.

§ 483.60(a). The second regulation requires facilities to provide each patient with high quality care in accordance with the patient's comprehensive assessment. Id. § 483.25. After determining that these infractions reached the level of "actual harm," CMS assessed a civil monetary penalty of \$250 per day from November 22, 2005 until Universal brought itself into compliance.

The December violations centered on A.W., a 69 year old patient who died the evening of November 3, 2005.² The survey team faulted Universal's staff for failing to monitor A.W.'s vital signs throughout the day. Had they done so, the survey concluded, the staff would have recognized that A.W. was declining rather than merely sleeping.

The parties dispute exactly what transpired on November 3. It is undisputed that A.W. awoke agitated and disoriented. After Valium was administered, he was observed to be sleeping. At 8:45 p.m., several nurses found A.W. to be non-responsive. They contacted his attending physician and family members, and they arranged for emergency medical services to transport A.W. to the hospital. A.W. died several hours later.

² Because CMS conducted two separate surveys, this resident is referred to as Resident #1, or R1B, in the record.

Following the December survey, CMS notified Universal that its treatment of A.W. violated three regulations. The first regulation requires that, in the event of a "significant change in the resident's physical, mental or psychological status," a facility must immediately inform the resident, consult with the resident's physician, and if known, notify the resident's legal representative or an interested family member. 42 C.F.R. § 483. The second regulation requires that a facility "develop and implement written policies and procedures that prohibit mistreatment and neglect." Id. § 483.13(c). CMS also found that Universal violated the quality of care regulation with respect to A.W.

After determining that these violations reached the level of "immediate jeopardy," CMS assessed a civil monetary penalty of \$300 per day from December 10, 2005 until Universal brought itself into compliance. CMS imposed an additional civil monetary fine of \$4,000 per day for the period November 3, 2005 through December 10, 2005.

Universal appealed CMS's findings and the penalties that it assessed. After a hearing, an ALJ affirmed the CMS's findings and penalties. Universal then took an appeal to the Department Appeals Board, which affirmed the ALJ's decision. The instant appeal followed.

II.

The appeal concerns two issues. The first is whether Universal violated the regulations as alleged with respect to the care given to G.J. and A.W. The Secretary's findings of fact must be upheld if they are supported by substantial evidence on the record as a whole. Woodstock Care Ctr. v. Health Care Fin. Admin., DAB No. 1726, at 9, 38 (2000), aff'd Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003). The Supreme Court has described "substantial evidence" in other contexts as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971).

On the second issue, Universal bears the burden of proving that CMS's determination of the level of noncompliance was clearly erroneous. See 42 C.F.R. § 498.60. We review for reasonableness as to the appropriate dollar value of the fines. See Woodstock Care Ctr., DAB No. 1726, at 43.

III.

The November 22, 2005 Survey focused on resident G.J., who, at that time, had resided at Universal since 1998. G.J. suffered from several ailments, including obsessive compulsive disorder, obstructive sleep apnea, cervical stenosis, and diabetes. G.J.'s sleep apnea required him to wear an airway

mask while sleeping. Frequently, G.J. would wake up with a headache. To address these headaches, in 1999, G.J.'s physician ordered that Cafergot pain tablets be administered to him every morning. By 2005, therefore, Cafergot had been an integral part of G.J.'s treatment plan for over five years.

On November 19, 2005, Nurse 1 was responsible for waking G.J. and administering his Cafergot.³ She discovered that, because of a clerical error, the pharmacy had run out of the medication. Instead, Nurse 1 gave G.J. Darvocet. When her shift ended at 7 a.m., she advised her replacement, Nurse 2, to immediately order Cafergot and administer it by mid-morning. Nurse 2, however, did not place an order for Cafergot until between 10 and 11 a.m.

Universal has an arrangement with a courier service that allows it to rapidly obtain emergency refills of medications. Had Nurse 2 taken appropriate action, the Cafergot would have arrived in the morning. Because of the delay, however, the Cafergot was not obtained or administered until 4:30 p.m. Meanwhile, G.J. found the Darvocet to be inadequate because he continued to complain of a headache, requiring Nurse 2 to give him Ultram.

³ The nurses' pseudonyms used here are taken from the record.

Universal is at fault for running out of Cafegot. This lapse, in and of itself, would not have triggered a penalty had the nursing staff followed Universal's policy and placed a rush order for the medication. Accordingly, Universal's defense centered on three points. First, that Darvocet and Ultram are adequate substitutes for Cafegot. Second, that upon discovering the Cafegot shortage, Nurse 1 called a doctor and administered Darvocet according to his instructions. Third, that Universal acted with sufficient alacrity.

The ALJ addressed all of these issues in his opinion. He concluded that Cafegot was required for G.J. because it was the only pain medication that relieved his frequent headaches. He rejected, as a finding of fact, Nurse 1's statement that she contacted a doctor who directed her to administer Darvocet. The ALJ concluded that this never happened. In a twenty-seven page written opinion, the Board affirmed all of the ALJ's findings.

The instant appeal reprises the same three arguments that the Secretary rejected. Universal's appeal relies heavily on the assertion that Nurse 1 called G.J.'s doctor promptly upon discovering that the Cafegot supply had run out and that she administered Darvocet according to the doctor's instructions. Universal argues that the ALJ and the Board simply ignored this telling evidence. This is not the case, however.

The record demonstrates that the ALJ expressly considered Universal's version of the facts and rejected it as implausible. In making this finding, he concluded that there was no evidence in the record to support Universal's assertion that a doctor had ordered Nurse 1 to administer Darvocet. The ALJ observed that G.J.'s attending physician testified at the hearing but said nothing about instructing a nurse to order Darvocet. He also noted that neither Nurse 1 nor any other witness with personal knowledge of the events of November 19 testified at the hearing. Finally, the ALJ observed that Nurse 1's note relating to the receipt of Darvocet was illegible. The Board concluded that the ALJ's decision to reject Universal's version of the events was reasonable and supported by substantial evidence.

On appeal, Universal repeats the three arguments that the Secretary rejected. The centerpiece of Universal's argument is its contention that upon discovering the shortage of Cafergot, Nurse 1 contacted a doctor. The ALJ's finding on this point is supported by substantial evidence. As the record demonstrates, the doctor's testimony did not corroborate Universal's version of the facts, the line on the nurse's medication notes is illegible, and Universal did not offer any testimony from the nurse. Ultimately, the ALJ was in the best position to conclude that the record as a whole does not support Universal's version of the facts.

The next issue is whether Darvocet was an adequate substitute for Cafergot. Universal would not be at fault if the two drugs were interchangeable. Here, both the ALJ and the Board reasonably concluded that they were not. This finding is fully supported by the record. For five years G.J. had received Cafergot exclusively, and he was on record as saying that Cafergot was the only drug that alleviated his headaches. Moreover, there is no evidence in the record as to the dosage of Darvocet given to G.J. Without evidence as to dosage, there is no basis on which to evaluate the pain reducing ability of the pill that G.J. took that morning. Moreover, the record shows that G.J. found the Darvocet to be inadequate because his headache continued and the staff administered Ultram later that morning.

The final issue is whether Universal, having run out of Cafergot, acted with sufficient alacrity to obtain a resupply. The record supports the Secretary's determination that Universal did not. Nurse 1 discovered the shortage at 5:00 a.m., but, despite Universal's ability to obtain an immediate resupply by courier, the Cafergot did not reach G.J. until 4:30 p.m. that afternoon.

Finally, we agree that the "actual harm" finding was not clearly erroneous because G.J. complained of pain all morning until he received the Cafergot.

IV.

The December 2005 survey centered on A.W., a 69-year-old patient who had been at the assisted living facility since July, 2004. A.W. suffered from many ailments, including a seizure disorder, dementia, agitation, and depression. CMS cited Universal for neglecting to assess and monitor significant changes to A.W.'s condition in violation of 42 C.F.R. § 483.13. CMS also cited Universal for failing to immediately notify A.W.'s physician and family of those changes in violation of 42 C.F.R. § 483.10(b)(11). Although there is some dispute as to what occurred during November 3, the survey and the ALJ agreed on the following facts.

A.W.'s attending physician, Dr. Newsome, had visited A.W. the previous night and observed that he was experiencing agitation. The next morning, Nursing Assistant 4 found A.W. confused, incontinent, and hungry. Nursing Assistant 4 retrieved A.W.'s breakfast and, upon returning, measured his blood pressure as 190/120. Nurse C, A.W.'s attending nurse, then called Dr. Newsome for instruction.⁴

Based on his observations from the night before, as well as the Nursing Assistant's report, Dr. Newsome ordered that Nurse C

⁴ "Nurse C" is used in this opinion as a pseudonym for the attending nurse.

administer Valium to A.W. Nurse C administered the Valium at approximately 10:15 a.m.

Throughout the day, Universal's staff checked on A.W. and observed that he was sleeping, which is what one would expect of a patient sedated with Valium. At 8:45 p.m., ten and a half hours after A.W. received the Valium, several nurses found A.W. unresponsive. They promptly called Dr. Newsome and A.W.'s family, and they arranged for emergency medical services to transport A.W. to the hospital. A.W. died several hours later. The cause of death was determined to be a hypersmolar coma with cerebal edema swelling and cerebal hernia.

Given this chronology, Universal contends that a finding of neglect is unsupported by the record. Universal claims that during these visits its staff observed A.W. sleeping, which would have been a normal reaction to Valium's sedative effects. The Secretary, concluded, however, that merely checking on A.W. was inadequate. Rather, the Secretary found that the change in A.W.'s condition on the morning of November 3 was sufficiently serious that Universal should have taken his vital signs throughout the day.

Despite Universal's protestations, this finding of neglect is fully supported by the record. The Secretary reasoned that A.W.'s agitation and disorientation placed the staff on notice that his condition was deteriorating. Because A.W. was sedated

with Valium, a casual inspection would reveal only that he was sleeping. Accordingly, the Secretary found that the staff should have monitored A.W.'s condition by regularly taking his vital signs so that they could respond to any untoward findings. The Secretary reasonably concluded that merely looking in on A.W. was insufficient. Moreover, the Secretary found that Universal had overstated the frequency with which its staff checked A.W. In an interview, Nurse C stated that she checked A.W. at least eight times during a twelve hour period. Because staff made no record of these visits, the ALJ reasonably discounted this recollection as an "after-the-fact reconstruction."

Because of Universal's failure to monitor A.W. adequately, the staff was unaware that he was deteriorating until 8:45 p.m. when he was found to be unresponsive. At that time, Universal immediately notified Dr. Newsome and A.W.'s family. By that late hour, however, Universal had already violated regulations requiring it to spot and promptly communicate significant changes in A.W.'s condition.⁵

⁵ This is not a medical malpractice case. The Secretary is not required to establish that A.W. would not have died had he been monitored more closely. The issue is not whether A.W.'s death was preventable but whether he received the care required by the regulations.

Finally, we affirm the Board's findings that the conditions at the facility created immediate jeopardy to residents' health and safety. The regulations define immediate jeopardy as a "situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment or death to the resident." 42 CFR § 488.404(b)(iv). The ALJ and the Board's findings were not clearly erroneous. To the contrary, Universal's failure to monitor and assess A.W.'s condition prevented Dr. Newsome from caring for his patient.

V.

Finally, we review the civil monetary penalties ("CMPs") assessed. Universal does not dispute the period for which CMS imposed penalties. Rather, Universal contends that the fines were unreasonable.

CMS may impose a CMP in two ways. It may either impose a per-instance CMP in the range of \$1,000 to \$10,000 or daily CMPs between \$3,050 and \$10,000. 42 CFR §§ 488.430, 488.438. Daily CMPs are appropriate for deficiencies that constitute immediate jeopardy to a facility's residents, and sometimes for repeated deficiencies. Id. § 488.438. Based on the two violations discussed herein, CMS imposed a CMP of \$4,000 per day for the

period November 3, 2005 through December 9, 2005 and a CMP in the amount of \$300 per day effective December 10, 2005.

These monetary penalties are appropriate. As discussed above, the finding of immediate jeopardy was not clearly erroneous. Accordingly, a daily CMP of \$4,000 is on the low end of the range permitted by the applicable regulations.

VI.

In sum, we conclude that the Secretary's determination that Universal was not in compliance with Medicare participation requirements was supported by substantial evidence. We also conclude that CMS's finding of immediate jeopardy was not clearly erroneous, and that the civil monetary penalties imposed were reasonable. Universal Healthcare's petition is, therefore,

DENIED.